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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,708	08/22/2001	Thomas Piccariello	54719.000028	6976

7590 03/18/2004

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,708	PICCARIELLO ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,13-17,20-34 and 36-134* is/are pending in the application.

4a) Of the above claim(s) *1-8,13-17,20-34,36-74 and 77-134* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *August 22, 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election with traverse of the species zidovudine in the Paper filed January 5, 2004 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the examiner to search the class of antivirals. This is not found persuasive because a proper response to an election of species requirement is that the species are not patentably distinct from one another. However, Applicants admit at page 2, lines 3-4, that the species are patentably distinct from one another. Further, because of the widely varying structures of the various antivirals, including proteins (e.g., interferon alfacon-1), protein conjugates (e.g., peginterferon alfa-2b), peptides (Thymosin alpha), nucleoside analogs (e.g., zidovudine), and non-carbohydrate heterocyclics (e.g., pleconaril), a search for one antiviral would not be likely to uncover relevant art for the other antivirals.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8, 13-17, 20-34, 36-74, and 77-134 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Paper filed January 5, 2004.

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

(a) An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or

continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Note that the declaration filed on January 11, 2002 refers to U.S. non-provisional application 09/642,820, but this application is not mentioned in the claim for priority contained in the preliminary amendment filed December 26, 2001.

(b) The claim for priority contained in the preliminary amendment filed December 26, 2001, uses the language "is a continuation in part of", to claim priority based upon numerous provisional applications. The language "is a continuation in part of" is language typically used to claim priority under 35 U.S.C. 120. While it is permitted to claim priority under 35 U.S.C. 120 based upon a provisional application , Applicants may not have intended to do so because this may have the effect of reducing the patent term of any patent which issues based upon this application. See MPEP 201.11(III)(B). Further, this language in the priority claim inserted into the specification contradicts the priority claim language in Applicants' Request For Corrected Filing Receipt filed January 11, 2002, which uses the language "claims priority of" and is language typically used to claim priority under 35 U.S.C. 119(e).

(c) Applicants need to review their priority claims, and need either to affirm that the priority claim contained in the preliminary amendment filed December 26, 2001 is the intended priority claim, or to submit a further amendment correcting the priority claim.

Note that any amendment to the priority claim will require a petition under 37 CFR 1.78(a). If the application is an application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or

sixteen months from the filing date of the prior application. If the application is a nonprovisional application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the reference to the prior application must be made during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). If applicant desires priority under 35 U.S.C. 120 or 119(e) based upon a previously filed application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). The petition must be accompanied by: (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted); (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Note that the requirement to petition applies when the relationship between parent applications is incorrectly stated, as well as when a priority claim is completely missing from an application. See the Notice by Deputy Commissioner Kunin dated February 24, 2003, at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/benefitclaims.pdf.

3. Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meaning of the compound name "BCX CW1812" at claim 76, line 3, is not

known. The name is not given any definition or chemical structure in the specification. The name is not used in the Merck Index, 13th edition, or in the U.S. patent database, and thus does not appear to have a well-established definition in the art.

4. Claim 76 is objected to because of the following informalities: At claim 76, line 5, a comma should be inserted after "nevirapine". At claim 76, line 7, a comma should be inserted after "sevirumab". Appropriate correction is required.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 98/04277. The WO Patent Application '277 teaches a prodrug of the formula recited at page 6, lines 1-21, in which a therapeutic agent, in particular AraC, didanosine, zidovudine, and stavudine, is attached via its amine group to the C-terminus of a peptide having from 2 to eleven amino acids. The amino acids in the peptide can be synthetic, and are chosen to control the rate of cleavage of the peptide from the therapeutic agent. In compound 19, the peptide is comprised of two different synthetic amino acids, Aib and Azagly, which peptide corresponds to Applicants' heteropolymer of two or more synthetic amino acids. The prodrugs can be administered orally. The WO Patent Application '277 also teaches attachment of the peptide to the therapeutic agent through a reactive hydroxyl function of the therapeutic agent. See, e.g., page 3, line 24 - page 4, line 2; page 6, lines 17-21; page 7, lines 19-21; page 7, line 29

- page 8, line 7; page 12, lines 17-19; page 15, lines 8-11; and page 16, lines 7-10. AraC, didanosine, zidovudine, and stavudine are antiviral agents.

7. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (U.S. Patent No. 5,534,496). Lee et al teach drugs which are covalently attached to a peptide. The drugs can be acyclovir and ganciclovir, which are antiviral agents. See, e.g., claims 1 and 7.

8. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Fiume et al (U.S. Patent No. 5,594,110). Fiume et al teach AZT covalently conjugated to lactosaminated human albumin. See, e.g., claims 1 and 2. Albumin is a polypeptide.

9. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Yatvin et al (U.S. Patent No. 5,965,519). Yatvin et al teach AZT covalently conjugated through a phosphate group to tetraglycine. See, e.g., Figure 8.

10. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al (U.S. Patent No. 5,965,695). Simon et al teach AZT covalently bound to a peptoid comprising 2 to 50 N-substituted glycine residues. See, e.g., claims 1 and 8.

11. Claim 75 is rejected under 35 U.S.C. 102(b) as being anticipated by Josephson et al (U.S. Patent No. 5,981,507). Josephson et al teach araA conjugated to polyglutamic acid. See, e.g., Table 1 and Example 35. AraA, i.e. vidarabine, is an antiviral agent.

12. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by the Japanese Patent Application Publication 2-59526. The Japanese Patent Application Publication '526 teaches AZT covalently conjugated to polypeptides such as antibodies, albumin, transferrin, lysozyme, fibrin, actin, myosin, poly-L-lysine, and poly-L-glutamic acid.

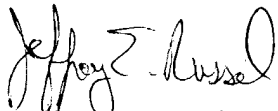
13. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by the Giammona et al article (J. Controlled Release, Vol. 54, pages 321-331). The Giammona et al article teaches zidovudine covalently conjugated to polyaspartamide. See, e.g., the Abstract and Scheme II, compound 4.

14. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by the Hussain et al article (Liebigs Ann. Chem., 1992, pages 169-171). The Hussain et al article teach AZT covalently conjugated to polypeptides comprised of lipidic amino acids. See, e.g., the abstract and page 169, column 1, compounds 3b-3e.

15. Claims 75 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by the Matsumoto et al article (Bioorganic & Medicinal Chemistry Letters, Vol. 10, pages 1227-1231). The Matsumoto et al article teaches AZT conjugated to a dipeptide comprising two different non-natural amino acids. See, e.g., Figure 4, Scheme 1, and Table 1.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
March 16, 2004